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ORIGINAL ARTICLE

Influence of the instrumented force shoe on gait pattern in patients with osteoarthritis of the knee

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Abstract Osteoarthritis (OA) of the knee is associated with alterations in gait. As an alternative to force plates, instrumented force shoes (IFSs) can be used to measure ground reaction forces. This study evaluated the influence of IFS on gait pattern in patients with knee OA. Twenty patients with knee OA walked in a gait laboratory on IFS and control shoes (CSs). An optoelectronic system and force plate were used to perform 3D gait analyses. A comparison of temporal-spatial gait parameters, kinematics, and kinetics was made between IFS and CS. Patients wearing IFS showed a decrease in walking velocity and cadence (8%), unchanged stride length, an increase in stance time (13%), stride time (11%) and step width (14%). No differences were found in knee adduction moment or knee kinematics. Small differences were found in foot and ankle kinematics (2–5°), knee transverse moments (5%), ankle frontal (3%) and sagittal moments (1%) and ground reaction force (1–6%). The gait of patients with knee OA was only mildly influenced by the IFS, due to increased shoe height and weight and a change in sole stiffness. The changes were small compared to normal variation and clinically relevant differences. Importantly, in OA patients no effect was found on the knee adduction moment.

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Abbreviations

OA	Osteoarthritis
IFS	Instrumented force shoe
KAdM	Knee adduction moment
GRF	Ground reaction force
CoP	Centre of pressure
CS	Control shoe
IMMS	Inertial and magnetic measurement system
RMSE	Root mean square error
SD	Standard deviation
BW	Body weight
H	Body height

1 Introduction

Osteoarthritis (OA) of the knee is a chronic degeneration of the joint which affects a substantial percentage of the elderly population [3]. Knee OA is often associated with alterations in temporal-spatial gait parameters, kinematics, and kinetics, such as a decrease in walking speed, reduced range of motion, a decrease in joint stability, varus/valgus malalignment of the joint, and a change in the net frontal knee moment (i.e. the external knee adduction moment: KAdM) [3–5, 12, 18, 28, 43, 45]. The KAdM reflects the distribution of load transferred through the medial versus the lateral compartment of the tibiofemoral joint [5, 12]. In studies identifying the severity of knee OA and evaluating progression and therapy, the KAdM has often been used as an outcome measure [5, 17, 26, 34, 40, 41, 43].

The temporal-spatial gait parameters, kinematics, and kinetics (including the KAdM) can be estimated from lower extremity gait measurements in a gait laboratory, using force plates to measure the ground reaction force (GRF) and an opto(-electronic) marker and camera system for 3D kinematic recordings of segment and joint orientation and position. However, the need for a special gait laboratory, the line of sight problems of optical markers, the restricted measurement volume, and high costs limit the clinical use of such lab-based systems. Furthermore, the need for (multiple) constrained foot placements on the force plates to measure the GRF could introduce adaptation of the gait pattern, which compromises the validity of the measurements [22, 36, 46].

Recently, ambulatory measurement systems have been introduced to measure kinematics and kinetics without such restrictions. To measure the kinematics of body segments, an inertial and magnetic measurement system (IMMS) has been developed [22, 32, 50]. Sensor units of the IMMS can be worn on the subject's body and provide kinematic information over many gait cycles [10, 14]. However, for an accurate measurement of kinetics such as the KAdM, or other lower extremity net joint moments, it is necessary to also measure the GRF and centre of pressure (CoP). For ambulatory assessment of GRF, an instrumented force shoe (IFS) has recently been developed [36]. The IFS is an orthopaedic sandal, equipped with two 6-degrees-of-freedom force/moment sensors under the heel and forefoot, respectively, which a sensor unit of the IMMS attached to each force sensor, at the lateral side of the sandal. The IFS has been evaluated for the assessment of GRF and ankle and foot dynamics in healthy subjects [21, 36], and for the estimation of the centre of mass (CoM) trajectory in stroke patients [37]. It has the potential for use in clinical practice, but the influence of the IFS on the gait pattern of patients with knee OA is still unknown. If wearing an IFS causes a significant and relevant modification of the gait pattern in these patients, it cannot be considered as an alternative way in which to measure the KAdM.

The aim of this study was therefore to evaluate the influence of wearing IFSs on the gait pattern of patients with knee OA, using a 3D gait measurement (with an optoelectronic marker system and force plate). We hypothesized that there would be no differences in temporal-spatial gait parameters, kinematics, or kinetics between walking on IFS and walking on control shoes (CSs).

2 Methods

2.1 Subjects

A total of twenty patients fulfilled the American College of Rheumatology (ACR) criteria for knee OA [2] and participated in the study [4 male, 16 female; age: 61(8.8) years; height: 1.67(0.12) m; body mass: 84(16) kg; body mass index 30.2(4.2); shoe size (French scale): 39.6(2.06)]. The patients had medial and/or lateral tibiofemoral radiographic OA, with a Kellgren/Lawrence grade of at least grade 1 [1, 19]. Sixteen patients had bilateral OA, and four had unilateral OA. They were recruited from the Reade Centre for Rehabilitation ad Rheumatology (Amsterdam, the Netherlands). The Medical Ethics Committee of the VU University Medical Center (Amsterdam, the Netherlands) approved the study protocol, and full written informed consent was obtained from all participants.

2.2 Procedure

Gait analysis of the patients was performed in a gait laboratory. The patients walked on a 10 m walkway at self-selected comfortable walking speed, first wearing the IFS, and subsequently the CS. Before measurement, the patients walked for several minutes to feel comfortable with the shoes. During the measurements, kinematic and kinetic data were collected by means of an optoelectronic marker system (OptoTrak 3020, Northern Digital Instruments, Waterloo, Canada) and a force plate (AMTI OR6-5-1000, Watertown, MA, USA). The movements of the trunk, pelvis, thighs, shanks, and feet were tracked, using technical clusters of three markers, anatomically calibrated [8], at a sample frequency of 50 Hz. Force plate data were collected with a sample frequency of 1000 Hz. Data on three successful trials (i.e. a foot placement within the outline of the force plate) were collected for each type of shoe.

2.3 Shoes

The IFSs [36] were orthopaedic sandals (Finn Comfort Prophylaxe 96200) equipped with two 6-degrees-of-freedom force/moment sensors (ATI mini45 SI-580-20, Schunk GmbH & Co. KG, Germany) under the heel and forefoot and two IMMS sensors (MTx inertial sensors, Xsens Technologies, Enschede, the Netherlands) at the lateral side of the

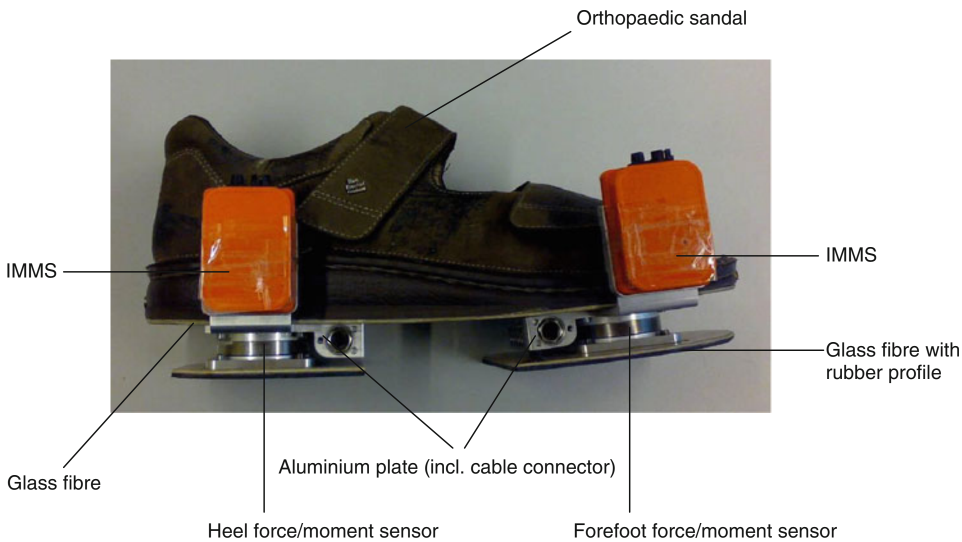

Fig. 1 The Instrumented Force Shoe. An orthopaedic sandal equipped with two force/moment sensors under the heel and forefoot and two sensors of the inertial and magnetic measurement system (IMMS) at the lateral side of the shoe, connected to the force/moment sensors via aluminium mounting plates. Sole-shaped glass fibre plates were placed between the shoe sole and the sensor mounting plates and under each sensor with a thin layer of rubber profile to provide friction with the floor. The glass fibre plates allowed motion in mainly longitudinal direction for a natural role off of the foot

sandal (Fig. 1). The IFS was available in sizes 38, 40 and 43 (French scale), and the total mass of one shoe (size 40) was approximately 1 kg. Whilst wearing the IFS, the patient also had to wear a small lightweight backpack (about 500 g) containing a custom-made amplifier, connected to the force/moment sensors, and an XbusMaster (Xsens Technologies, Enschede, the Netherlands) with a wireless connection to the computer (not used in this study, since only the force plate data was used). Due to the two force/moment sensors, the IFS sole was elevated with about 2 cm.

The CSs were the same type of orthopaedic sandals as the IFS (Finn Comfort Prophylaxe 96200, sizes 38, 40 and 43). The total mass of one shoe (size 40) was 372 g.

2.4 Data analysis

Optoelectronic marker data and force plate data were analysed using BodyMech (www.BodyMech.nl), custom-made software based on MATLAB (Version 7.2.0.232 (R2006a)). Data on three successful trials per patient per side per shoe were averaged.

Force plate data and foot velocity profile for other steps were used to determine initial contact (IC) and toe-off (TO) in the gait cycle [30]. Temporal-spatial gait parameters were calculated, including walking velocity (m/s), stance time (s), stride time (s), stride length (m), step width (m), and cadence (steps/min).

The kinematic patterns of each gait cycle, including the 3D segment and joint angles in degrees (foot, ankle, knee, hip, pelvis, trunk), were calculated from the optoelectronic data, using ISB anatomical frames [8, 48], and time-normalized to 100% of the gait cycle. The kinematic parameters, obtained from the kinematic patterns of the gait cycle, included the minimum, maximum and mean value and the range of the time-normalized kinematic waveforms (i.e. maximum–minimum). In addition, the dorsiflexion of the ankle in late stance, the plantar flexion of the ankle at IC and TO and the stance phase knee flexion were included in the analysis. These parameters are known to be affected by walking speed [42], and any effect of a possible change in walking speed on these parameters needs to be investigated. The midstance knee varus/valgus angle was also included, because of its importance to the KAdM.

The kinetics included the 3D external knee moments (also the KAdM), 3D external ankle moments, GRF and CoP. The kinetic patterns were calculated from force plate and optoelectronic data and time-normalized to 100% of the stance phase. The joint moments were obtained using inverse dynamics [49], expressed with respect to the proximal segment anatomical frame [35], and normalized to body weight (N) and body height (including shoe height), i.e. % BW*H (or Nm/(N*m)*100) [27]. GRF was normalized to body mass (i.e. N/kg). The CoP (cm) was expressed with respect to the coordinate system of the foot. The kinetic parameters included the minimum, maximum and mean value and the range of the time-normalized kinetic waveforms. The peaks in early and late stance and the midstance value of both the vertical GRF and the KAdM were also included in the analysis, since these parameters are known to be affected by walking speed [42] and are of special interest with regard to the KAdM.

Four outcome measures were used to assess the similarity in kinematic and kinetic patterns whilst wearing the IFS and the CS. First, the root mean square error (RMSE) of the time-normalized kinematic and kinetic waveforms of the IFS versus the CS was calculated as follows:

$$\text{RMSE} = \sqrt{\frac{1}{N}\sum_{n=1}^{N}(\text{IFS}(n)-\text{CS}(n))^2 \text{ (with } n \text{ being sample number).}}$$

The RMSE was expressed with respect to the average range (maximum–minimum) and with respect to the standard deviation (SD) of the three trials whilst wearing the CS (i.e. an expression of the variability within a subject). For the kinematics, RMSE was considered to be good when <3° (based on inter-trial variability of gait analysis systems [38]) and within the normal range of the CS (<2 SD CS). For the kinetics, RMSE was considered to be good when <10% CS, and within the normal range of the CS (<2 SD CS), based on variability seen in the KAdM in OA patients [12]).

Second, the offset of the kinematic patterns (in degrees) of the IFS versus the CS was calculated:

$$\text{Offset} = \frac{1}{N}\sum_{n=1}^{N}(\text{IFS}(n)-\text{CS}(n))$$

The offset was considered to be good when <3° (based on inter-trial variability of gait analysis systems [38]).

Third, the gain of the kinetic patterns (dimensionless) between the IFS and the CS was calculated:

$$\text{Gain} = \frac{\sum_{n=1}^{N}(\text{IFS}(n)\cdot\text{CS}(n))}{\sum_{n=1}^{N}(\text{CS}(n))^2}$$

$$\text{(linear regression without intercept [16]).}$$

The gain was considered to be good between 0.9 and 1.1.

Finally, the correlation coefficients (Pearson R) of the time-normalized kinematic and kinetic patterns (of the gait cycle) between IFS and CS were calculated. Correlations were considered to be good when >0.8, moderate 0.7–0.8 and poor <0.7 [47].

3 Statistical analysis

Statistical differences in the temporal-spatial gait parameters, the kinematic parameters and the kinetic parameters between the IFS and the CS were calculated in SPSS Software Version 15.0.

The paired sample t test was used to determine whether the walking velocity, cadence and step width differed significantly between walking on the IFS and walking on the CS. Repeated measures analysis of variance (ANOVA, SPSS Software Version 15.0) was used to determine whether the difference in stance time, stride time and stride lengths were significantly different. Repeated measures ANOVA was also used to determine whether the differences in kinematic and kinetic parameters between the IFS and CS were significant. The model included the shoe type (IFS or CS), the leg type (right or left) and their interaction. Using this repeated measure design, the model corrected for the leg type (since both right and leg left values were included). When an interaction is significant, the effect of shoe type is different in the right leg compared to the left leg.

Furthermore, analysis of covariance (ANCOVA) was used to account for walking velocity as a covariate, since it may affect the kinematic and kinetic parameters [42]. Finally, backward linear regression analyses were used to assess whether significant changes found in the kinematic or kinetic parameters could be associated with a change in any of the temporal-spatial parameters. In these analyses, the change in kinematic or kinetic parameter was the dependent variable, and the changes in temporal-spatial parameters were the independent variables. Statistical significance was determined as a P-value of less than 0.05.

4 Results

4.1 Temporal-spatial gait parameters

Table 1 describes the differences in temporal-spatial gait parameters between IFS and CS. Walking velocity was significantly lower when wearing the IFS (8%, $P = 0.004$). This was expressed only in the cadence (−8%, $P < 0.000$), and not in the stride length ($P = 0.996$). Consequently, stance time and stride time were significantly longer (13 and 11%, $P < 0.000$). Step width was significantly larger (14%, $P = 0.049$).

5 Kinematics

The RMSE values, offsets and correlation coefficients of the time-normalized kinematic waveforms whilst walking on the IFS versus the CS, averaged over the subjects, are presented in Table 2. On average, the RMSE values in joint and segment angles were less than 6° and less than 3 SD of the CS. The offsets were less than 1.3°.

The RMSE values of the knee angles in the sagittal and transverse plane were higher than 3°, but less than 2 SD of the CS. The RMSE of the frontal knee angle was less than 2°. The correlations between the IFS and CS knee

Table 1 Difference in temporal-spatial gait parameters of the IFS versus the CS

Temporal-spatial gait parameters	IFS	CS	Difference		Significance
	Mean (SD)	Mean (SD)	Mean (SD)	% Range CS (mean (SD))	*P*
Velocity (m/s)	0.94 (0.16)	1.02 (0.17)	−0.08 (0.10)	−8.0 (9.5)	0.004*
Cadence (steps/min)	93.2 (8.94)	102 (9.46)	−8.43 (4.88)	−8.3 (4.9)	0.000*
Stance time (s)	0.86 (0.13)	0.77 (0.09)	0.10 (0.07)	12.6 (9.3)	0.000*
Stride time (s)	1.31 (0.16)	1.19 (0.13)	0.12 (0.09)	10.5 (8.0)	0.000*
Stride length (cm)	121 (14.2)	121 (15.7)	−0.20 (8.73)	−0.2 (7.2)	0.966
Step width (cm)	16.2 (3.95)	14.3 (5.14)	1.92 (3.00)	13.5 (21.0)	0.049*

IFS instrumented force shoe; *CS* control shoe; *SD* standard deviation

$^*P < 0.05$

kinematic waveforms were good (>0.8), and mean offset values were below 1°.

The highest RMSE values were found for the ankle and foot angle in the frontal plane (i.e. in/eversion), with differences of approximately 6° (i.e. ±3 SD of the CS) and poor to moderate correlation coefficients (<0.8). The mean offset values were around 1°, but a large variation was seen (offset SDs ±5°). Ankle and foot angle correlations in the transverse plane (i.e. exo/endorotation) were also poor to moderate (<0.8), with the RMSE slightly higher than 3°.

The RMSE of foot, ankle and hip angles in the sagittal plane were higher than 3° (foot angle >5°), and for the ankle higher than 2 SD of the CS. The correlations between the IFS and CS kinematic waveforms were good (>0.8), and the mean offset values were below 1°. The sagittal trunk angle (i.e. trunk tilt) had a very small range and a RMSE of less than 3°, with a poor correlation (<0.7).

Table 3 presents the differences in kinematic parameters of walking with the IFS versus the CS ($P < 0.05$). The differences were all less than 2 SD CS. No significant differences were found in the knee kinematic parameters of the IFS versus the CS. Maximal foot dorsal flexion in the sagittal plane decreased with the IFS (±4°; on average 1.5 SD). A significant interaction was found between leg and shoe type in the range of the foot angle in the sagittal plane, i.e. the range decreased for the right leg (10°), but not for

Table 2 RMSE, offset and correlations in kinematic patterns (°) of the IFS versus the CS

Kinematics	Plane	RMSE			Offset	Correlation
		Degrees (°) Mean (SD)	% Range CS Mean (SD)	SD CS Mean (SD)	Degrees (°) Mean (SD)	Pearson *R* Mean (SD)
Trunk	Sagittal	2.2 (1.3)	68.1 (41.6)	1.1 (0.9)	0.7 (2.3)	0.59 (0.26)[a]
	Frontal	1.4 (0.6)	34.3 (22.4)	1.5 (0.9)	−0.3 (1.3)	0.83 (0.19)
	Transversal	2.1 (1.2)	24.1 (14.4)	1.8 (0.8)	0.5 (1.9)	0.94 (0.06)
Pelvis	Sagittal	2.0 (1.4)	45.8 (38.0)	2.1 (1.3)[a]	−0.5 (1.6)	0.71 (0.22)[a]
	Frontal	1.3 (0.58)	16.9 (6.7)	1.5 (0.7)	0.0 (0.8)	0.92 (0.09)
	Transversal	2.0 (1.1)	22.2 (10.6)	1.3 (0.7)	−0.4 (1.2)	0.81 (0.24)
Hip	Sagittal	3.4 (2.3)[a]	9.1 (6.9)	1.7 (1.0)	0.8 (3.0)	0.97 (0.07)
	Frontal	1.7 (0.7)	12.2 (6.0)	1.6 (0.8)	0.1 (1.1)	0.96 (0.05)
	Transversal	2.9 (2.0)	22.9 (15.7)	1.8 (1.7)	0.8 (2.8)	0.82 (0.15)
Knee	*Sagittal*	3.8 (2.0)[a]	6.0 (3.1)	1.6 (1.0)	−0.1 (3.1)	0.98 (0.03)
	Frontal	1.7 (1.0)	15.7 (10.6)	1.8 (1.5)	0.5 (1.5)	0.87 (0.15)
	Transversal	3.3 (2.5)[a]	19.9 (11.8)	1.7 (1.0)	0.4 (2.2)	0.83 (0.12)
Ankle	Sagittal	4.7 (1.9)[a]	16.9 (8.07)	2.2 (1.5)[a]	−0.3 (2.9)	0.87 (0.13)
	Frontal	5.1 (2.9)[a]	42.4 (28.5)	3.0 (2.6)[a]	−1.1 (5.1)	0.67 (0.34)[a]
	Transversal	3.9 (1.8)[a]	26.9 (10.6)	1.9 (1.0)	−1.3 (2.7)	0.66 (0.25)[a]
Foot	Sagittal	5.6 (2.5)[a]	8.8 (10.6)	1.6 (0.9)	0.3 (2.6)	0.97 (0.04)
	Frontal	5.8 (3.1)[a]	41.6 (26.4)	2.9 (2.7)[a]	−0.7 (5.8)	0.75 (0.18)[a]
	Transversal	4.0 (1.8)[a]	28.8 (9.7)	1.6 (0.8)	−0.3 (3.3)	0.77 (0.18)[a]

IFS instrumented force shoe; *CS* control shoe; *RMSE* root mean square error; *SD* standard deviation

[a] RMSE > 3°, SD CS > 2 or $R < 0.8$

the left leg. No significant difference was found in ankle plantar/dorsal flexion, although there was an interaction effect which showed an increase in plantar flexion and range, only for the left leg (4°). The decrease in ankle endorotation was less than 3°. Although some differences in hip, pelvis and trunk kinematics appeared to be significant, all were less than 2°. There was no significant effect of the shoe type on any of the kinematic parameters after controlling for walking velocity. Backward linear regression analyses showed no association of change in any of the temporal-spatial parameters with changes in the kinematic parameters.

6 Kinetics

Figure 2 shows the external frontal knee moments (KAdM) and sagittal knee moments of 4 patients whilst walking on the IFS (solid line) and the CS (dashed line). The KAdM differs between the patients, showing a variation within the patient group.

The RMSE values, gains and correlation coefficients of the time-normalized kinetic waveforms of IFS versus CS, averaged over the patients, are presented in Table 4. On average, the RMSE was below 1.77 SD of the CS, and the gain varied between 0.87 and 1.02.

The KAdM in the stance phase of the IFS was highly correlated with the CS, and the RMSE was less than 10% of the range and 1.34 SD of the CS. The gain of the external transverse knee moment (0.87) showed a reduced range in knee endo/exorotation moment. Although the sagittal knee moment (i.e. flexion/extension moment) had a RMSE of 18% of the range of the CS, the RMSE was less than 2 SD of the CS, the gain was good and the correlation was high.

Fig. 2 Knee moments. Net external frontal knee moment (KAdM) ▶ and sagittal knee moment of 4 patients during stance phase whilst walking on the Instrumented Force Shoe (IFS; solid line) and the Control Shoe (CS; dashed line). Each moment curve is the average of three trials of the right leg of the patient. The moments are normalized to bodyweight (BW in N) and body height (H in m)

The correlation between the CoP trajectory of the IFS and the CS over the entire stance phase in medio-lateral direction was poor (<0.7), but a high correlation was found in forward direction (>0.8). The RMSE of the CoP trajectory in forward direction was approximately 5% of the length of the shoe.

Table 5 presents the differences in kinetic parameters of the IFS versus the CS ($P < 0.05$). The differences were all less than 2 SD CS. No systematic differences between the IFS and the CS were found in the KAdM parameters (i.e. maximal adduction and abduction moment, mean value, range, and peaks in early and late stance and midstance value). In the transverse plane, the decrease in range of the external knee moment was more than 10%, corresponding with the low gain (0.87). The correlation between the IFS and the CS was good (Table 4: $R > 0.8$).

The maximal ankle adduction moment was reduced by almost 3% with the IFS. No differences were found in ankle sagittal moments, although an interaction effect between leg and shoe type showed an increased external ankle dorsal flexion moment in only the left leg (3%) and a decreased external ankle plantar flexion moment, only in the right leg (1%). There was no significant effect of the shoe type on any of the joint moment parameters after controlling for walking velocity. Backward linear regression analyses showed no association of a change in any temporal-spatial parameter with changes in joint moments.

Peak values of the vertical GRF (sagittal plane) in early and late stance increased by about 2% when wearing the

Table 3 Differences ($P < 0.05$) in kinematic parameters (°) of the IFS versus the CS

Kinematics	Plane	Parameter	Difference (IFS − CS)			Significance
			Degrees (°) Mean (SD)	% Range CS Mean (SD)	SD CS Mean (SD)	P
Trunk	Sagittal	Range	0.7 (0.8)	23.2 (80.1)	0.4 (1.4)	0.004
Pelvis	Frontal	Maximal drop	−0.2 (1.1)	−4.5 (14.4)	−0.7 (1.3)	0.016
		Range	−0.7 (1.3)	−7.7 (18.7)	−1.0 (1.7)	0.047
Hip	Sagittal	Maximal extension	−0.9 (3.1)	−2.2 (8.1)	−0.9 (1.8)	0.003
	Frontal	Maximal abduction	−0.7 (2.3)	−3.6 (10.7)	−0.6 (1.6)	0.017
		Range	−0.8 (2.6)	−2.8 (17.9)	−1.0 (2.3)	0.020
	Transversal	Maximal exorotation	−1.5 (3.4)	−10.1 (25.0)	−1.0 (2.6)	0.020
Ankle	Transversal	Maximal endorotation	−2.8 (5.1)	−15.4 (30.6)	−1.1 (2.9)	0.025
Foot	Sagittal	Maximal dorsal flexion	−4.0 (6.8)[a]	−5.8 (8.3)	−1.5 (2.6)	0.033

IFS instrumented force shoe; *CS* control shoe; *SD* standard deviation

[a] Difference > 3°

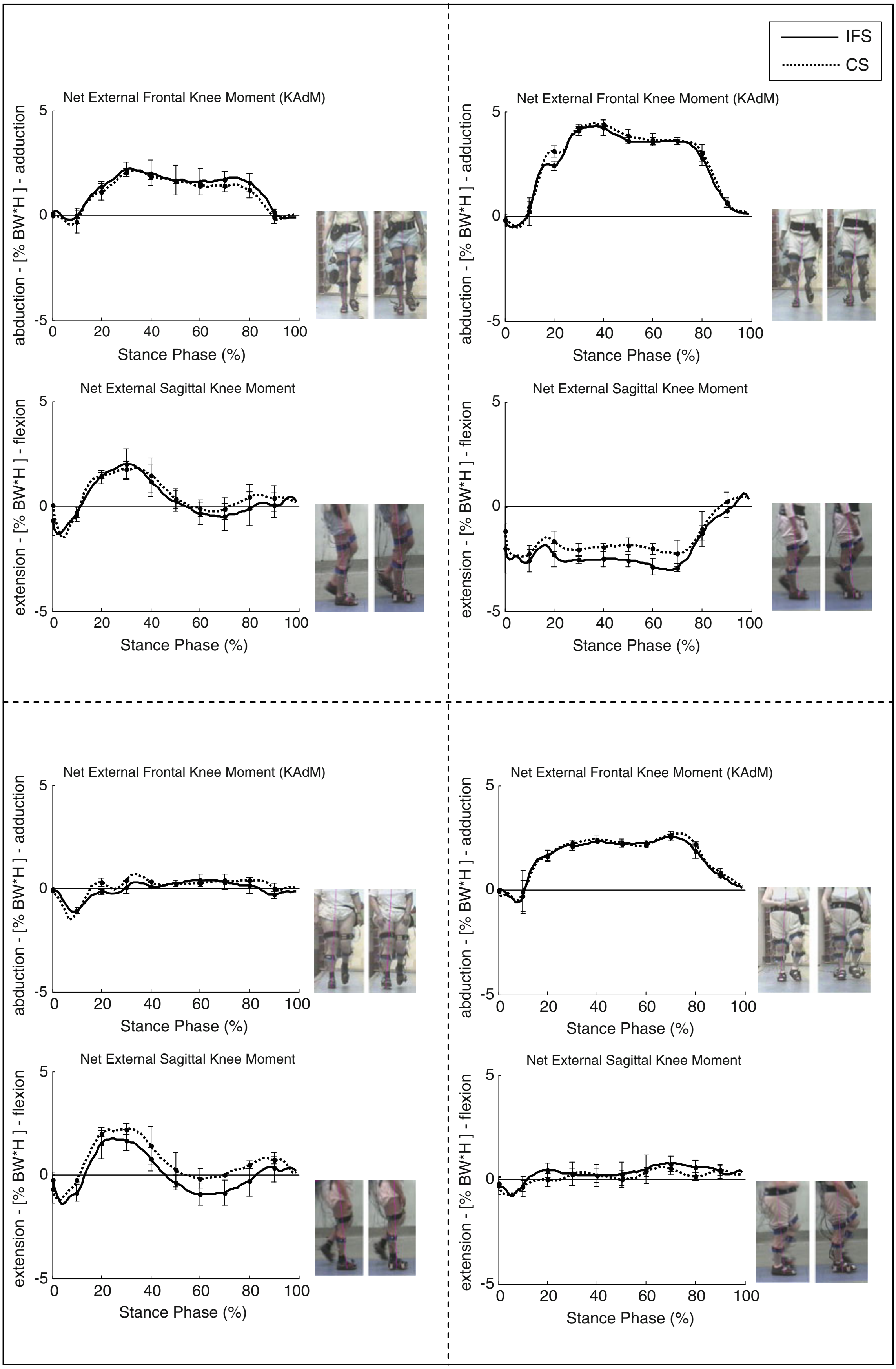
IFS
CS
Net External Frontal Knee Moment (KAdM)
abduction - [% BW*H] - adduction
Stance Phase (%)
Net External Sagittal Knee Moment
extension - [% BW*H] - flexion
Stance Phase (%)
Net External Frontal Knee Moment (KAdM)
abduction - [% BW*H] - adduction
Stance Phase (%)
Net External Sagittal Knee Moment
extension - [% BW*H] - flexion
Stance Phase (%)
Net External Frontal Knee Moment (KAdM)
abduction - [% BW*H] - adduction
Stance Phase (%)
Net External Sagittal Knee Moment
extension - [% BW*H] - flexion
Stance Phase (%)
Net External Frontal Knee Moment (KAdM)
abduction - [% BW*H] - adduction
Stance Phase (%)
Net External Sagittal Knee Moment
extension - [% BW*H] - flexion
Stance Phase (%)

Table 4 RMSE, gain and correlations in kinetic patterns of the IFS versus the CS

Kinetics	Plane	RMSE			Gain	Correlation
		Value Mean (SD)	% Range CS Mean (SD)	SD CS Mean (SD)	Mean (SD)	Pearson R Mean (SD)
Knee moment (% BW*H)	Frontal (KAdM)	0.28 (0.10)	9.58 (3.65)	1.34 (0.46)	1.00 (0.12)	0.96 (0.04)
	Transversal	0.06 (0.03)	10.9 (4.02)[a]	1.41 (0.72)	0.87 (0.17)[a]	0.94 (0.04)
	Sagittal	0.63 (0.27)	18.4 (8.20)[a]	1.67 (1.09)	0.91 (0.32)	0.91 (0.09)
Ankle moment (% BW*H)	Frontal	0.23 (0.10)	20.4 (12.8)[a]	1.22 (0.69)	0.90 (0.39)	0.85 (0.15)
	Transversal	0.05 (0.03)	8.79 (3.90)	1.13 (0.68)	0.98 (0.14)	0.97 (0.03)
	Sagittal	0.46 (0.21)	5.69 (2.85)	1.27 (0.83)	1.02 (0.06)	0.99 (0.02)
GRF (N/kg)	Post. – Ant.	0.19 (0.06)	6.04 (1.52)	1.45 (0.59)	0.93 (0.07)	0.98 (0.01)
	Vertical	0.66 (0.22)	6.51 (2.33)	1.53 (0.59)	1.01 (0.02)	0.97 (0.02)
	Medio-lateral	0.10 (0.04)	11.1 (3.58)[a]	1.07 (0.39)	1.00 (0.13)	0.94 (0.04)
CoP (cm)	Post.– Ant.	1.24 (0.70)	6.83 (4.87)	1.77 (1.19)	0.98 (0.07)	0.98 (0.04)
	Medio-lateral	0.87 (0.51)	18.5 (10.4)[a]	1.74 (1.38)	0.97 (0.68)	0.57 (0.37)[a]

IFS instrumented force shoe; *CS* control shoe; *RMSE* root mean square error; *SD* standard deviation; *BW* body weight in Newtons; *H* body height in metres

[a] RMSE % Range CS > 10%, Gain < 0.9 or $R < 0.8$

Table 5 Differences ($P < 0.05$) in IFS versus the CS

Kinetics	*Plane*	Parameter	Difference (IFS − CS)			Significance
			Value Mean (SD)	% Range CS Mean (SD)	SD CS Mean (SD)	P
Knee moment (% BW*H)	Transversal	Maximal exorotation	−0.04 (0.06)	4.84 (10.5)	0.61 (1.54)	0.002
		Maximal endorotation	−0.04 (0.07)	−6.03 (13.0)	−0.87 (2.03)	<0.001
		Range	−0.08 (0.10)	−10.5 (16.5)[a]	−1.47 (2.78)	<0.001
Ankle moment (% BW*H)	Frontal	Maximal adduction	−0.06 (0.15)	−2.78 (15.4)	−0.39 (0.98)	0.032
GRF (N/kg)	Post. – Ant.	Maximum anterior	−0.20 (0.15)	−6.28 (4.73)	−1.58 (1.39)	<0.001
		Range	−0.20 (0.27)	−6.17 (8.90)	−1.66 (2.16)	0.003
	Vertical	Peak 1	0.18 (0.35)	1.83 (3.41)	0.39 (0.88)	0.027
		Midstance	0.34 (0.29)	3.22 (2.75)	0.80 (0.75)	<0.001
		Peak 2	0.18 (0.31)	1.79 (2.96)	0.41 (0.74)	0.004
		Mean	0.14 (0.20)	1.31 (1.95)	0.34 (0.50)	0.001
		Maximum	0.16 (0.32)	1.62 (3.13)	0.35 (0.73)	0.018
	Medio-lateral	Maximum lateral	−0.04 (0.11)	−2.68 (12.1)	−0.37 (1.15)	0.027
CoP (cm)	Medio-lateral	Range	−0.65 (2.45)	−9.75 (40.0)	−1.22 (4.84)	0.004

IFS instrumented force shoe; *CS* control shoe; *SD* standard deviation; *BW* body weight in Newtons; *H* body height in metres

[a] % Range CS > 10%

IFS, and the vertical GRF in midstance increased by 3%. The anterior shear force of the GRF in late stance was 6% less in the IFS, and the lateral shear forces of the GRF in early stance were 3% less in the IFS. After controlling for walking velocity, no significant effect was found of shoe type on the vertical GRF in midstance and on the range of the anterior shear force and the maximal anterior shear force in late stance. The backward linear regression analyses showed that the increase in vertical GRF in midstance was associated with the decrease in walking velocity (beta = −0.497, $P = 0.002$) and the increase in stride time (beta = 0.336, $P = 0.032$). The decrease in anterior shear force was associated with the decrease in walking velocity (range: beta = 0.367, $P = 0.039$; maximal: beta = 0.362, $P = 0.042$). No associations were found of changes in temporal-spatial parameters with the other changes in GRF.

There was a decrease in range of the CoP in the medial/lateral direction, which is in line with the RMSE value. For the left shoe, the CoP was positioned more medially (0.4 cm).

7 Discussion

7.1 Temporal-spatial gait parameters

Liedtke et al. [21] found no significant differences in temporal-spatial gait parameters between normal shoes, heavy shoes and IFS in young healthy adults. In our study, the walking velocity of the OA patients decreased by 8% (0.08 m/s) when walking on the IFS. A change of at least 0.12 m/s in walking speed in patients with knee OA is considered to be clinically important [6, 13]. Therefore, the decrease in walking speed due to wearing the IFS could be regarded as below clinical relevance.

Usually, a decrease in walking velocity is reflected in a decrease in both cadence and stride length [9]. The unchanged stride length in our study implies that kinematics, after normalizing for stride time, were unlikely to be affected by a change in walking velocity. Indeed, the backward linear regression showed no effect of changes in temporal-spatial gait parameters on the kinematic parameters. However, an effect of the change in walking velocity was found on the vertical GRF in midstance (IFS 3% higher) and the anterior GRF force (IFS 6% lower), which is consistent with results reported in the literature [42].

Step width increased with 2 cm (14%) when walking on the IFS. Greater step width variability has been found with increasing age: older adults tend to control the CoM within their base of support by adjusting their step width to compensate for poor balance [7]. This may explain the increase in step width in the patients in our study when walking on the IFS. The healthy adults in the study from Liedtke et al. [21] did not show a significant wider step width whilst walking on the IFS, indicating that these younger healthy subjects did not have to use the control mechanism to compensate for poor balance. Furthermore, the step width of the healthy adults was smaller compared to the step width of the OA patients.

The force sensors under the IFS increased the height of the shoe by about 2 cm. Heels with an elevation of more than 2.5 cm impair balance in older people [23], reduce walking velocity [25], alter the stance phase [11], decrease the stride length [24] and influence the KAdM [15]. It is not evident that this also applies to the IFS, since the entire shoe is elevated (not only the heel). In another study, plantar pressure insoles have been used to estimate 3D GRF to avoid the influence of changed interface between the shoe and the ground [33]. In this approach, the limitations of an IFS in clinical applications can be further reduced.

7.2 Kinematics

In our study, we found no systematic differences in knee kinematic parameters, and only small differences were found in foot and ankle kinematic parameters. Differences in hip, pelvis and trunk angles were all less than 2^{o}, and not considered to be relevant with regard to the inter-trial variability of gait analysis systems [38]. It shows that wearing the IFS had no great influence on the kinematics of the OA patients.

Maximal foot dorsal flexion (with respect to the global coordinate system) was systematically decreased with the IFS (4^{o}). There are two main reasons that could explain the difference in the foot dorsal flexion. First, a difference in the position of the optoelectronic cluster markers could cause a difference in kinematics. Although the same virtual markers (i.e. the anatomical points inferred from the cluster) were used for the kinematic calculations, the cluster of the CS was placed on top of the mid-foot (metatarsals) whereas the cluster of the IFS was placed on the IMMS heel sensor, which is connected to the hind-foot. In doing so, we assumed the foot to be one rigid segment. However, the literature suggests that this assumption is not always valid. The kinematic behaviour of the foot might need three segments: hind-, mid- and fore-foot [29]. An error of marker cluster placement is expected if a significant amount of movement between hind- and mid-foot occurs, which is probably the case in the role-off dynamics of the foot during stance. Second, the force sensors under the shoe cause an increase of 2 cm in height of the entire shoe, as well as an increase of 600–700 g in the mass of each shoe. Due to the additional height and mass, the leg inertial properties changed, and could consequently affect the kinematics of gait when considering gait as a pendulum movement [39]. Since such changed inertial properties of the leg could have required more muscle force (e.g. to propel the leg forward), this additional effort might have been problematic for OA patients, as reflected in the lower walking velocity, in contrast to healthy subjects, who were well able to walk at the same velocity on the IFS [21].

7.3 Kinetics

The KAdM is an important kinetic variable because of its association with load on the articular cartilage in the knee joint and its use in the evaluation of disease severity and treatment [5]. The results showed no systematic difference in KAdM between the IFS and the CS. The RMSE (<10% CS and <2 SD CS) was within the normal range of variability reported in other studies [12]. This confirms that wearing the IFS has no influence on the KAdM in patients with OA.

The KAdM is mainly determined by the magnitude of the GRF and the lever arm, the latter being determined by the position of the CoP and the knee joint centre, and the direction of the GRF. With the IFS, an increase was found in the vertical GRF over the entire stance phase, and the lateral GRF vector in early stance decreased. Although a significant effect of shoe type was found on the range of the medio-lateral CoP, no significant changes were found in the frontal knee kinematic parameters. The changes in walking velocity, step width and GRF, and the additional height of the IFS caused no significant change in the KAdM. The increase in midstance of the vertical GRF was related to the decrease in walking velocity and the increase in stride time, which is consistent with reports in the literature [42].

A reduced range of the knee moment in the transversal plane occurred with the IFS (11%), which was also expressed by a low gain (<0.9). This was correlated with the decrease in lateral and anterior GRF. The decrease in anterior GRF (6%) was related to the decrease in walking velocity (which is consistent with earlier reported effects [42]). The small change in the frontal ankle moment (3%) was most likely due to a change in the medio-lateral CoP.

Although the increase in midstance of the vertical GRF and the decrease in the anterior GRF were related to the decrease in walking velocity, the increase in vertical GRF in early and late stance and the decrease in lateral GRF in loading response were not related to any change in temporal-spatial parameters. The increase in peak vertical GRF in early and late stance, and the decrease in lateral GRF in loading response with the IFS are probably consequences of the design of the IFS sole. The stiffness of the sole is different because of the glass fibre plates, and the non-flexible force/moment sensors could cause a different role and push-off, as reflected by the CoP.

7.4 Implication

The IFS has the potential for use in clinical practice, because the influence on the gait pattern in the OA patients is small compared to normal variation and clinically relevant differences. In particular, no significant changes were found in the KAdM, and the patients found walking on the IFS comfortable. Moreover, when an IFS is used for gait analysis, it should be kept in mind that it will create significant differences compared to walking barefoot, comparable to wearing shoes of any kind [20].

However, an optimization of the design of the shoe needs to be considered to furthermore reduce the effect on the gait pattern when using the IFS in clinical setting. This can be achieved using smaller and lighter force/moment sensors or insoles, a more appropriate choice of sole material, and the fabrication of different shoe sizes which are an exact fit for all patients.

The patient population in this study included patients with a diversity in OA severity (Kellgren/Lawrence grade), and patients with more pronounced medial OA, as well as patients with more pronounced lateral OA. Such a heterogeneous patient population was included, since the IFS should be a good measurement tool for all severities of knee OA. However, we did not analyse whether the effect of the IFS would be different with an increase in Kellgren/Lawrence grade, or with a difference in location of the radiographic knee OA features, because of a lack of recent X-rays of some patients (<6 months old), as well as a resulting small size of each of the different groups. Furthermore, the Kellgren/Lawrence grade is a global score, that does not take into account the exact location of the OA (per knee compartment), and does not separate all the different radiographic features of OA, such as osteophytes, joint space narrowing, cysts and sclerosis.

The IFS would be ideal for use when no gait laboratory or force plates are available in a clinic or centre, or to collect data from multiple strides. However, to determine the KAdM, not only the GRF must be known, but also additional information is required about the position of the knee joint centre. Without using an optoelectronic marker system to indicate joint positions and orientations, the IMMS sensors on shoe and shank, which measure only orientation, need to be anatomically calibrated [10, 31, 44] and used in combination with a biomechanical model to estimate the joint positions. Since the results of our study show that the IFS has no negative influence on the gait pattern, the next step would be to validate the use of a combination of the IFS, several IMMS sensors and the biomechanical model to calculate the KAdM in OA patients in an ambulatory setting, compared to the results from common inverse dynamics from force plate and opto(-electronic) marker system data. After such a validation, gait analysis aimed at the KAdM in adults will no longer be restricted to a gait laboratory.

To conclude, the results of this study have demonstrated that the gait pattern in patients with knee OA was mildly affected by the IFS. The differences in gait parameters whilst walking on the IFS versus the CS mainly concerned the consequence of an increase in shoe height and mass and a change in sole stiffness. Changes in temporal-spatial parameters, kinematics, and kinetics were small, compared to normal variation and clinically relevant differences. No effect was found on the external KAdM or on knee kinematics.

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